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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions,

and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 81 FR 54091-54094, dated August 15, 2016) is amended to reflect the reorganization of the Division of Healthcare Quality and Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Office of Infectious Diseases, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete and replace the title and the mission and function statements for the Division of Healthcare Quality and Promotion (CVLD) and insert the following:

Division of Healthcare Quality Promotion (CVLD). Protects patients and healthcare personnel, and promotes safety, quality, and value in both national and international healthcare delivery systems. In carrying out its mission, Division of Healthcare Quality Promotion (DHQP): (1) Measures, validates, interprets, and responds to data relevant to healthcare-associated infections (HAI); antimicrobial use and resistant infections, sepsis, adverse drug events, blood, organ and tissue safety, immunization safety, and other related adverse events or medical errors in healthcare affecting patients and healthcare personnel; (2) investigates and responds to emerging infections,

antimicrobial resistance, and related adverse events among patients and healthcare personnel; (3) develops and maintains the National Healthcare Safety Network (NHSN), a tool for monitoring healthcare-associated infections, antimicrobial use and resistance, measuring healthcare outcomes and processes, and monitoring healthcare worker vaccination and selected health measures in healthcare facilities;

(4) assesses local, regional, national scope and burden of infections caused by resistant-bacteria in the U.S. through surveillance and special studies, review of national healthcare data sets, and laboratory surveillance programs; (5) conducts epidemiologic, and basic and applied laboratory research to identify new strategies to monitor and prevent infections/antimicrobial resistance, and related adverse events or medical errors, especially those associated with medical or surgical procedures, indwelling medical devices, contaminated products, dialysis, healthcare environment, and water;

(6) collaborates with academic and public health partners to design, develop, and evaluate new approaches to monitoring infections and the efficacy of interventions for preventing infections, improving antibiotic use, and reducing antimicrobial resistance, and related adverse events or medical errors; (7) develops and disseminates evidence-based guidelines and recommendations to prevent and control HAI, antimicrobial resistance (AR), and related adverse events or medical errors; (8) collaborates with Federal, state, and local public health and private partners to promote nationwide implementation of CDC guidelines and other evidence-based interventions to prevent HAI, antimicrobial resistance, and related adverse events or medical errors among patients and healthcare personnel; (9) evaluates the impact of evidence-based recommendations and interventions across the spectrum of healthcare delivery sites; (10) serves as the

Designated Federal Official for the Healthcare Infection Control Practices Advisory Committee (HICPAC); (11) serves as the National Reference Laboratory for the identification and antimicrobial susceptibility testing of staphylococci, anaerobic bacteria, non-tuberculous mycobacterial, and those gram-negative bacilli causing healthcare-associated infections; (12) serves as the technical reference laboratory for detection and characterization of other pathogens related to healthcare, and for characterizing the contribution of the healthcare environment to HAI and antimicrobial resistant infections; (13) serves as a global resource for HAI, antimicrobial resistance, and device-associated HAI; (14) coordinates guidance and research related to infection control across CDC and with national and international partners; (15) monitors vaccine safety and conducts research to evaluate the safety of available and new vaccines; (16) trains EIS Officers and other trainees; (17) coordinates antimicrobial resistance activities at CDC; (18) works in a national leadership capacity with public and private organizations to enhance antimicrobial resistance prevention and control, surveillance and response, and applied research; (19) coordinates blood, organ, and other tissue safety at CDC; and (20) provides expertise and assistance to HHS, other Federal agencies, and global partners on efforts and activities related to safe healthcare.

Office of the Director (CVLD1). (1) Manages, directs, and coordinates the activities of DHQP; (2) provides leadership and guidance on policy impacting patient and healthcare safety; (3) leads targeted patient safety communication campaigns coordinated with release of CDC surveillance data, infection control guidelines, research publications, and prevention tools; (4) fosters strategic partnerships with clinical professional organizations to advance implementation of CDC's recommendations and best clinical

practices; (5) leads communication/media outreach to include social media platforms and CDC's patient and healthcare safety websites, (6) works with Federal agencies, international organizations, and other partners on activities related to safe healthcare; (7) coordinates state and local activities to monitor and prevent HAI and antimicrobial resistance; (8) coordinates activities related to infection control in healthcare and related settings including, guideline development and maintenance, interim guidance development, training, consultation, and international activities across DHQP, CDC, and with national and international partners; (9) coordinates DHQP activities and collaborates with the CDC EOC for emergency response to emerging infections in healthcare; (10) coordinates DHQP activities and collaborates with other CIOs and Federal agencies to prepare healthcare to respond to emerging threats; (11) oversees the quality of DHQP research activities and identifies research gaps; (12) leads CDC's activities on blood, organ, and other tissue safety; (13) represents CDC on the Advisory Committee on Blood Safety and Availability, and the Advisory Committee on Organ Transplantation; (14) works with other Federal agencies, state governments, and other public and private organizations to enhance blood, organ, and other tissue safety through coordination of investigation, prevention, response, surveillance, applied research, health communication, and public policy; (15) provides leadership and guidance for program planning and development, program management, and operations; (16) provides DHQP-wide administrative and program services, and coordinates or ensures coordination with the appropriate CIOs and CDC staff offices on administrative and program matters including, budget formulation and execution, and human resource management; (17) oversees the coordination of Federal and state programs and new initiatives to prevent HAI and

antimicrobial resistance; (18) interprets general program and administrative policy directives for implications on management and execution of DHQP's programs; (19) serves as lead, primary contact, and liaison with relevant CDC Staff Offices on all matters pertaining to DHQP's procurement needs and activities; (20) provides management and coordination for DHQP-occupied space and facilities including laboratory space and facilities; (21) provides oversight and management of the distribution, accountability, and maintenance of CDC property and equipment including laboratory property and equipment; (22) provides program and administrative support for HICPAC; and (23) advises the Director, NCEZID, on science, policy and communication matters concerning DHQP activities.

Antimicrobial Resistance Coordination and Strategy Unit (CVLD13).

(1) Oversees the coordination of AR activities at CDC to meet national goals; (2) represents CDC in interagency activities on AR including the President's Advisory Committee for Combatting Antibiotic Resistant Bacteria (PAC-CARB); (3) coordinates with other agencies, state governments, medical societies, and other public and private organizations to enhance AR prevention and control, surveillance and response, and applied research; (4) represents CDC at the Transatlantic Task Force on Antimicrobial Resistance (5) oversees CDC AR budget to implement AR activities as part of the Federal Action Plan to Combat Antibiotic Resistant Bacteria; (6) coordinates policies and communications associated to CDC-wide programs related to AR; (7) ensures coordination with appropriate CIOs and CDC staff offices on AR program matters, including budget formulation and execution; (8) provides updates and reports about CDC AR activities and progress to the CDC Director, HHS, and the White House; and (9)

oversees coordination of CDC collaborations and new Federal initiatives to detect, respond and prevent antimicrobial resistance.

International Infection Control Activity (CVLD14). (1) Leads, in collaboration with the appropriate CIO and CDC components, global health activities related to the prevention of HAI, antimicrobial resistance, and related adverse events or medical errors; (2) coordinates international efforts to establish and improve infection prevention and control policies, programs, and coordination; (3) assists countries to improve infection prevention and control capacity toward prevention and control of HAI disease outbreaks and device-associated HAIs; (4) collaborates with ministries of health, CDC country offices, and implementing partners, to develop country-specific national policies and action plans to reduce the global burden of antimicrobial resistance associated with healthcare delivery; and (5) provides technical assistance to partners in building antimicrobial resistance laboratory capacity and surveillance systems.

Clinical and Environmental Microbiology Branch (CVLDB). (1) Leads national laboratory characterization of HAI-related threats in partnership with state and regional laboratories; (2) provides comprehensive laboratory support and expertise for investigations of recognized and emerging pathogens in healthcare settings, such as methicillin-resistant *S. aureus*, carbapenem-resistant Enterobacteriaceae (CRE), and *Clostridium difficile*; (3) provides laboratory response to outbreaks and emerging threats associated with infections/antimicrobial resistance and related adverse events throughout the healthcare delivery system; (4) develops methods to assess contamination of environmental surfaces; (5) investigates novel and emerging mechanisms of antimicrobial resistance among targeted pathogens found in healthcare settings;

(6) conducts research in collaboration with partners to develop new, accurate methods of detecting antimicrobial resistance in bacteria and to improve reporting of antimicrobial susceptibility test results to physicians to improve antimicrobial use; (7) conducts laboratory research to identify new strategies to prevent infections/antimicrobial resistance, related adverse events, and medical errors, especially those associated with invasive medical devices, contaminated products, dialysis, and water; (8) maintains capacity to evaluate commercial microbial identification, antimicrobial susceptibility testing systems and products, and facilitates their improvement to provide accurate patient test results; (9) investigates the role of biofilms, particularly those detected in indwelling medical devices and medical water systems, in medicine and public health, and identifies novel methods to eliminate colonization and biofilm formation on foreign bodies;

(10) investigates the role of microbiome in the prevention of infections and antimicrobial resistance; (11) investigates the role of the water distribution systems in healthcare facilities in order to understand and prevent transmission of healthcare-associated infections due to water; and (12) provides expertise, research opportunities, training, and laboratory support for investigations of infections and related adverse events to other CDC CIOs and to our partners in areas related to quality clinical microbiology laboratory practices, investigation of emerging pathogens, and environmental microbiology.

Prevention and Response Branch (CVLDC). Across the healthcare continuum, including acute, long-term, ambulatory, and chronic care settings: (1) develops, promotes, and monitors implementation of evidence-based recommendations, standards, policies, strategies and related educational materials to prevent and control HAI, and

related adverse events, and healthcare personnel safety events associated with antibiotic resistance, device, and procedure associated infections, poor adherence to quality standards and safety, and emerging infectious diseases; (2) develops, promotes, and monitors implementation of and adherence to evidence-based recommendations, standards and related educational materials, policies and strategies to increase adherence to appropriate antimicrobial use and stewardship; (3) uses data from the National Healthcare Safety Network (NHSN) and other sources to target and improve the prevention and control healthcare-associated infections and antimicrobial resistance in the U.S. in specific regions, settings and institutions; (4) supports local, state, and national efforts to prevent HAI, antimicrobial resistance, and related adverse events by providing leadership and consultative services, including monitoring adherence to CDC-recommended practices; (5) provide leadership and epidemiologic support for the investigation, monitoring, and control of both recognized and emerging healthcare pathogens, including antimicrobial resistant bacteria; (6) leads response and control of outbreaks and emerging threats involving HAI and related adverse events, contaminated medical products and devices, and adverse drug events; (7) communicates the results of response activities with Federal and state agencies, healthcare providers, and the public, with recommendations to prevent similar adverse events in the future; and (8) provides leadership and expert consultation, guidance, and technical support to and collaborates with other CDC CIOs and divisions, other HHS Operating Divisions, and extramural domestic partners, on the epidemiology, prevention, and control of HAI, AR, and related adverse events; (9) implements state activities to prevent HAI and AR across healthcare; and (10) leads CDC activities to promote antimicrobial stewardship in all healthcare

settings.

Surveillance Branch (CVLDD). (1) Monitors and evaluates on the national level the extent, distribution, and impact of HAI, antimicrobial use and resistance, adverse drug events, healthcare worker safety events, and adherence to clinical processes and intervention programs designed to prevent or control adverse exposures or outcomes in healthcare; (2) provides services, including leadership, consultation, and analysis support, for statistical methods and analysis to investigators in the branch, division, and other organizations responsible for surveillance, research studies, and prevention and control of HAI and other healthcare-associated adverse events; (3) works with the Centers for Medicare and Medicaid Services and other partners to develop new metrics and support maintenance of National Quality Forum-approved metrics (4) collaborates with public and private sector partners to further standardize, integrate, and streamline systems by which healthcare organizations collect, manage, analyze, report, and respond to data on clinical guideline adherence, HAI, including transmission of multi-drug resistant organisms, and other HAI; (5) coordinates, further develops, enables wider use, and maintains NHSN to obtain scientifically valid clinical performance indices that promote healthcare quality and value at the facility, state, and national levels; (6) develops and implements new NHSN modules and provides enrollment and user support for NHSN; (7) improves surveillance systems by utilizing new technology; (8) generates and provides NHSN surveillance reports and analyses, which include collaborative analytic projects with partners; and (9) leads CDC's national adverse drug events surveillance activities and seeks to translate population-based surveillance data into evidence-based policies and targeted, innovative and collaborative interventions.

Immunization Safety Office (CVLDE). Assesses the safety of new and currently available vaccines received by children, adolescents and adults using a variety of strategies: (1) conducts ongoing surveillance for the timely detection of possible adverse events following immunization (AEFI) in collaboration with the Food and Drug Administration (FDA) , through coordination and management of the Vaccine Adverse Event Reporting System, the national reporting system that acts as an early-warning system to detect health conditions that may be associated with immunization; (2) coordinates, further develops, maintains and directs activities of the Vaccine Safety Datalink (VSD), a collaborative effort with integrated healthcare organizations, to conduct surveillance and investigate possible AEFI to assess causality and determine risk factors; (3) conducts epidemiologic research on causality of AEFI using the VSD and other data sources, and provides national estimates of incidence of AEFI and background rates of health conditions; (4) leads the nation in developing biostatistical methods for research of AEFI using large linked databases and other data sources, and shares methods for use by other Agencies and public and private entities; (5) conducts clinical research to identify causes of adverse events after immunization, specific populations susceptible to specific adverse events, and prevention strategies through the Clinical Immunization Safety Assessment network, a national network of medical research centers, and other efforts; (6) applies findings from epidemiologic and clinical studies to develop strategies for prevention of AEFI; (7) provides global consultation and leadership for the development, use, and interpretation of vaccine safety surveillance systems, and for the development of shared definitions of specific health outcomes through participation in the Brighton Collaboration and other international organizations; (8) provides data for

action to HHS, the Advisory Committee on Immunization Practices, the FDA's Vaccine and Related Biological Products Advisory Committee, Health Resources and Services Administration's Advisory Commission on Childhood Vaccines, and collaborators around the globe including the WHO Global Advisory Committee on Vaccine Safety; and (9) provides timely, accurate communication and education to partners and the public on vaccine safety concerns.

Epidemiology Research and Innovations Branch (CVLDG). (1) Identifies and evaluates the efficacy of interventions to prevent HAI and related adverse events or medical errors across the spectrum of healthcare delivery sites including acute and long-term inpatient care, dialysis, and ambulatory settings; (2) identifies gaps in HAI-related knowledge, and conducts prevention research through the Prevention Epicenters cooperative agreements program and Safety and Healthcare Epidemiology Prevention Research Development research contracts; (3) conducts and supports research and evaluates impact of public health practices to prevent HAI, antimicrobial resistance, and related adverse events; (4) improves methods and enables wider use of clinical performance measurements by healthcare facilities and public health entities for specific interventions and prevention strategies designed to safeguard patients and healthcare workers from risk exposures and adverse outcomes through collaborations with extramural partners; (5) conducts applied research to identify and develop innovative methods to detect and monitor HAI and antimicrobial resistance; (6) conducts special studies to identify key risk factors for and provides national estimates of targeted, healthcare-associated adverse events, antimicrobial use and resistance patterns, and the extent to which prevention and control safeguards are in use to protect at-risk patients

across the spectrum of healthcare delivery sites; (7) develops new ways to assess the impact of HAI prevention programs; (8) conducts analysis of the return on investment and costs related to prevention efforts and impact of HAI prevention programs; and (9) works with the Emerging Infections Program (EIP) and other partners to identify emerging issues.

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